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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,363	06/15/2001	Eugene J. Alexander	3104/105	6739

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EXAMINER	
FOREMAN, JONATHAN M	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/882,363	ALEXANDER ET AL.	
	Examiner	Art Unit	
	JONATHAN ML FOREMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-72 and 75-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-72 and 75-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

Terminal Disclaimer

1. The terminal disclaimer filed on 12/13/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 11/410,515 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 69 – 72 and 75 – 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 69 and 80 begin with the preamble "A method of treating a human with a joint disease involving cartilage, the method comprising:". However, the claimed method is directed to a diagnosis and contains no step directed to treating a human. It is unclear how the method treats a human with a joint disease when there are no steps associated with treating.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 69, 70, 75 – 81 and 84 – 89 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,682,886 to Delp et al.

In regard to claims 69, 70, 75 – 81 and 84 – 89, Delp et al. disclose obtaining an electronic image of a joint (Col. 8, lines 33 – 61), wherein the image includes both normal and diseased cartilage tissue; electronically evaluating the image to obtain information including at least one of volume, area, thickness, shape, curvature geometry, biochemical contents, signal intensity and relaxation time of the normal and/or diseased tissue; and determining biomechanical data associated with the joint (Col. 8, line 63 – Col. 10 - 53). The biomechanical data includes at least one axis associated with the joint, the at least one axis associated with a femoral condyle coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis (Col. 11, lines 49 – 51). The biomechanical data includes at least one axis associated with the joint, the at least one axis associated with a tibial coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis (Col. 11, lines 49 – 51). The biomechanical data includes static loading alignment in that the data is determined during a static loading position. The data is displayed. Delp et al. disclose using the information to shape an implant (Col. 12, line 63 – Col. 14, line 63).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 69, 70, 71, 76, 80, 81, 82 and 86 rejected under 35 U.S.C. 103(a) as being unpatentable over by Kshirsager et al. (Investigative Radiology, vol. 33, no. 5) in view of U.S. Patent No. 5,682,886 to Delp et al.

In regard to claims 69, 70, 71, 76, 80, 81, 82 and 86, Kshirsager et al. disclose obtaining an electronic image of a joint, wherein the image includes both normal and diseased cartilage tissue; electronically evaluating the image to obtain information including at least one of volume, area, thickness, shape, curvature geometry, biochemical contents, signal intensity and relaxation time of the normal and/or diseased tissue; and determining biomechanical data associated with the joint (Page 290, "Image Processing"). The biomechanical data includes static loading alignment in that the data is determined during a static loading position. Kshirsager et al. teach determining biomechanical data during joint motion (Page 298, Col. 1). The data is displayed. However, Kshirsager et al. fail to teach the biomechanical data includes at least one axis associated with the joint, the at least one axis associated with a femoral condyle coordinate system or a tibial coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. However, Delp et al. teach a method of obtaining an electronic image of the joint and determining at least one axis associated with a femoral condyle coordinate system or a tibial coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis (Col. 11, lines 49 – 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method disclosed by Kshirsager et al. to include the determining of at least one axis as taught by Delp et al. in order to create a better 3d model of the joint and to better diagnose the joint. Furthermore, the claim would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time

of the invention to apply the technique of determining at least one axis as taught by Delp et al. to improve the method of Kshirsager et al. for the predictable result of creating a 3d image having correct anatomical relationships.

9. Claims 77, 78, 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kshirsager et al. in view of U.S. Patent No. 5,682,886 to Delp et al., and further in view of U.S. Patent No. 6,203,546 to MacMahon.

In regard to claims 77, 78, 87 and 88, Kshirsager et al. in view of Delp et al. disclose the data being derived from a degenerative knee by an MRI but fail to disclose using the data to provide a therapy in the form of shaping an implant. However, MacMahon teach therapy for a degenerative joint in the form of shaping an implant using data derived from an MRI (Col. 5, lines 33 – 45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Kshirsager et al. in view of Delp et al. to include providing a therapy in the form of shaping an implant as taught by MacMahon in order to provide the patient with a custom made implant to fit precisely within the joint.

10. Claims 72 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kshirsager et al. in view of Delp et al.

Kshirsager et al. in view of Delp et al. teach determining data during joint motion, but fail to disclose the joint motion being during a patient's gait. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Kshirsager et al. in view of Delp et al. to determine data during a gait cycle of a patient in order to analyze the patient during a typical unconstrained movement.

11. Claims 69, 70, 76, 80, 81 and 86 are rejected under 35 U.S.C. 103(a)) as being unpatentable over U.S. Patent No. 6,560,476 to Pelletier et al. in view of U.S. Patent No. 5,682,886 to Delp et al.

In regard to claims 69, 70, 76, 80, 81 and 86, Pelletier et al. disclose obtaining an electronic image of a joint, wherein the image includes both normal and diseased cartilage tissue; electronically evaluating the image to obtain information including at least one of volume, area, thickness, shape, curvature geometry, biochemical contents, signal intensity and relaxation time of the normal and/or diseased tissue; and determining biomechanical data associated with the joint (Col. 9, lines 48 – 51; Col. 12, lines 46 – 56). The biomechanical data includes static loading alignment in that the data is determined during a static loading position. The data is displayed. Pelletier et al. fail to teach the biomechanical data includes at least one axis associated with the joint, the at least one axis associated with a femoral condyle coordinate system or a tibial coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. However, Delp et al. teach a method of obtaining an electronic image of the joint and determining at least one axis associated with a femoral condyle coordinate system or a tibial coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis (Col. 11, lines 49 – 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method disclosed by Pelletier et al. to include the determining of at least one axis as taught by Delp et al. in order to create a better 3d model of the joint and to better diagnose the joint. Furthermore, the claim would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of determining at least one axis as taught by Delp et al. to improve the method of Pelletier et al. for the predictable result of creating a 3d image having correct anatomical relationships.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736